510(k) Summary

In accordance with section 513(I) of the SMDA and as defined in 21 CFR Part 807.3 final rule dated December 14, 1994, this summary is submitted by:

Kendall, a Division of Tyco Healthcare
15 Hampshire Street
Mansfield, MA 02048
Date Prepared: 29 January 2010

MAY - 4 2010

1. Contact Person

Mia Proli
Manager, Regulatory Affairs
(508) 261-8037

2. Name of Medical Device

Classification Name: Sleeve, Limb, Compressible
Proprietary Name: Kendall SCD™ Sequential Compression Comfort Sleeves

3. Identification of Legally Marketed Device

The proposed devices, Sequential Compression Comfort Sleeves, are identical in intended use, function and mode of operation to the SCD Express System Sleeves (K040511); SCD Express Tear-Away Sleeves (K040649) and SCD Large/X-Large Knee and Thigh Sleeves (K051805).

4. Device Description

The proposed devices, Sequential Compression Comfort Sleeves, are the compressible limb sleeve component of a pneumatic compression system for applying pressure to a patient's leg for the prevention of deep vein thrombosis (DVT) and pulmonary embolism (PE).

Sequential Compression Comfort Sleeves are compatible with the SCD Express Controller (K040511), SCD Response Controller (K992079) and SCD Sequel Controller (K942664), collectively referred to as SCD Controllers. SCD Controllers provide air to the sleeves through tubing connected to each bladder of the sleeve delivering an intermittent, sequentially gradient pneumatic pressure to the limb. The controller system monitors the pressure in the bladders and releases the pressure by venting the air from the sleeve bladders through a valve system within the controllers.

The proposed single-patient-use, disposable sleeves are available in knee, thigh and thigh Tear-Away styles. The Tear-Away function allows the clinician to convert the patient from a thigh length sleeve to a knee length sleeve without changing to a new sleeve. The sleeve connects to a controller via a 3-lumen tubing set. The tubing set connects to the sleeve via a low-profile connector that can be disengaged to allow for patient ambulation without sleeve removal.

5. Device Intended Use

The Kendall SCD Compression System is designed to increase venous blood flow in the at risk patient, including bariatric and morbidly obese patients, in order to help prevent deep vein thrombosis and pulmonary embolism.

6. Product Comparison

The proposed devices, Sequential Compression Comfort Sleeves, are identical in intended use, function and mode of operation to the SCD Express System Sleeves (K040511); SCD Express Tear-Away Sleeves (K040649) and SCD Large/X-Large Knee and Thigh Sleeves (K051805).

The predicate SCD Sleeves are constructed of two layers of non-woven polyester laminated to a thin film of PVC that are welded together to form bladders. Tubes are attached to the bladders via rigid PVC inlet ports which are welded to the laminate material. To make the sleeves more comfortable, the proposed Comfort Sleeves will be constructed of four layers; two layers of non-laminated PVC welded together to form bladders with covers made from both a polyester mesh fabric and a wickable polyester fabric, which form a "pillowcase" around the bladders. In this design, the tubing will be welded into the bladders, beneath the sleeves, without the use of an inlet port.

7. Product Testing

There are no FDA performance standards established and required for the proposed device. However, the standards listed in the table below have been reviewed and applied in whole or in part as deemed appropriate during design, development, and manufacture of the proposed device:

Standard Number	Standard Title	Version
ISO 10993-1	Biological Evaluation of Medical Devices Part 1: Evaluation and Testing	2003
ISTA 2A	ISTA Preshipment Testing Procedures – Combination Tests for Packaged Products	2008

Product verification and validation testing as detailed in this 510(k) submission was used to demonstrate equivalence of the proposed device. Such testing included basic functional and performance tests, along with hemodynamic testing on healthy human subjects.

Intermittent pneumatic compression systems (IPC), such as the Kendall SCD Compression System, have been used clinically by healthcare professionals for over twenty years. A review of published and unpublished clinical literature identifies no major risks associated with these devices. Extensive published clinical experience with these devices confirms an acceptable risk/benefit ratio and provides substantial clinical evidence to support the following conclusions:

1. Sufficient clinical literature and data exist to demonstrate the safety and performance of IPC devices.
2. The objectives of the clinical review were met by an analysis of all relevant aspects of safety and performance reported in scientific literature and no gaps of information are present.
3. All of the published reports examined for the clinical review are from recognized scientific, peer-reviewed journals and address the indications of the devices.

4. The literature reveals little variation in the clinical indications for the use of the devices under review.
5. The literature and the narrative review provide critical evaluation of the hazards and risks and appropriate safety measures for the devices with respect to patients, medical staff, and third parties.
6. The patient/study populations reported in the literature, the medical purpose, indications for use, and types of diseases reported are those intended for the devices.
7. The literature reviewed addresses the technology, critical performance, design, current state of the art and principles of use and features of the devices as well as competing products and technology.
8. No references are identified which indicate the presence of risks inherent to the design.
9. The claims made in the device labelling are substantiated by the published clinical data.

8. Conclusion

Product verification and validation testing and a review of clinical literature demonstrate that Kendall Sequential Compression Comfort Sleeves are as safe, as effective and perform as well as the predicate devices.

Sequential Compression Comfort Sleeves are substantially equivalent to the predicate devices in the following areas:

- Both the proposed and predicate devices are intended to be used with the SCD Express Controller (K040511), SCD Response Controller (K992079) and SCD Sequel Controller (K942664).

- When connected to a compression system, both the proposed and predicated devices are compressible limb sleeves designed to increase blood flow by applying pressure to a patient's limb for the prevention of deep vein thrombosis and pulmonary embolism.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Covidien
c/o Mia Proli
Manager, Regulatory Affairs
15 Hampshire Street
Mansfield, MA 02048

MAY - 4 2010

Re: K100306
Kendall SCD™ Sequential Compression Comfort Sleeves
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: January 29, 2010
Received: February 3, 2010

Dear Ms. Proli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K100306

Device Name: Sequential Compression Comfort Sleeves

Indications for Use: The Kendall SCD Compression System is designed to increase venous blood flow in at risk patients, including bariatric and morbidly obese patients, in order to help prevent deep vein thrombosis and pulmonary embolism.

Prescription Use __X__ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Please Do Not Write Below This Line – Continue On Another Page If Needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100306